Remarks

The Applicants thank the Examiner for withdrawing claim rejections under 35 U.S.C. § 102(b) over Addicks et al. (US PG-Pub 2001/0043945), 102(e) over Straub et al. (US Patent 6,395,300) and 103(a) over Straub et al (US Patent 6,395,300) or Addicks at al. (US PG-Pub 2001/0043945) in view of Pankhania et al. (US Patent 5,415,871) made in the Office action dated June 7, 2008 based on the reply filed by the Applicants on October 30, 2007.

The Applicants have considered the comments the Examiner has made in the Office Action dated January 18, 2008 and address the rejections made by the Examiner through these remarks and certain amendments to the claims (appended to these remarks). Applicants request withdrawal of the rejections in the Office Action dated January 18, 2008, in view of the above amendments, and following remarks.

Claims 1, 6, 7, 9-13, 16-27, 45-46 and 49-51 are pending with claims 1, 27 and 45 being independent.

Claims 1, 9, 11, 27 and 45 have been amended. All amendments, which have been indicated separately, are supported by the specification. No new matter has been added.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 1, 6, 7, 9-13, 16-27, 45-46 and 49-51 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner has said that the use of the phrases "one or more" and "wherein the hydrophilic polymers comprise a combination of cellulose ether and a carbohydrate gum" make it

unclear as to how many polymers the Applicants are claiming as required in the composition.

In order to bring clarity, the Applicants have amended the claims to delete the phrase 'one or more'. The Applicants believe that the amendments make the number of hydrophilic polymers used in the composition clear and finite and adequately address this rejection.

Rejection under 35 U.S.C. § 103(a) over Dilantin® Physician Information sheet in view of Vandecruys et al. (US Patent 6,667,060)

Claims 1, 6, 7, 9-13, 16-27, 45-46 and 49-51 have been rejected as being unpatentable over Dilantin® Physician Information sheet (Dilantin® PI) dated September 2007 in view of Vandecruys et al. (US Patent 6,667,060, referred to as 'Vandecruys' herein after) for obviousness.

The Examiner says that Dilantin® PI discloses phenytoin sodium 100 mg Extended Release Oral Capsules wherein "the product is supplied as hard, filled no. 3 capsules containing a white powder. The Examiner goes on to say that "[T]he Dilantin Information Sheet does not disclose a hydrophilic polymer is added to the phenytoin powder". (Jan 18, 2008 Office Action, page 3).

The Examiner then says "Vandecruys discloses a controlled release composition comprising hydrophilic controlled release matrix polymers" in the Abstract and that "[T]he hydrophilic polymers include hydroxypropylmethylcellulose, hydroxypropylcellulose, and tragacanth, agar, guar, xanthan, for example". The Examiner then goes on to assert that it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of the Dilantin®

PI with the teachings of Vandecruys in order to provide a controlled pharmacokinetic release profile for a preparation. The Applicants respectfully traverse.

The Dilantin® Product Information Sheet the examiner has cited is dated September 2007 and does not qualify as prior art to this Application, which has a priority date of December 16, 2002 (Indian patent application number 1264/DEL/2002) . Therefore, any obviousness rejection based on the Dilantin® PI is improper and must be withdrawn.

However, the Applicants will respond to the Examiner's rejection assuming that there is such a label which would properly constitute prior art.

The Dilantin® PI merely discloses a powder-filled capsule and various ingredients used in the formulation. As the Examiner has admitted, it does not mention the use of any hydrophilic polymer in the composition; neither does it provide any information on how the product is formulated. All three independent claims – claims 1, 27 and 25 – pending in the instant Application have several limitations apart from requiring a powder blend of phenytoin sodium. In determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious (MPEP 2141.02, emphasis in the original).

Vandecruys discloses controlled release formulations that necessarily contains pregelatinized starch (Abstract). In fact, Vandecruys repeatedly asserts that controlled release formulations comprising hydrophilic polymers result in dose-dumping and that only the use of pregelatinized starch prevents such dose-dumping (for example, please

see the abstract; column 3, lines 45-49; column 4, lines 7-31; column 5, lines 1-22). The need to use pregelatinized starch to achieve controlled release is repeatedly emphasized (column 8, lines 23-24; column 10, lines 33-34). All examples but one use pregelatinized starch. There is one example of a formulation that does not contain pregelatinized starch (column 20, lines 22 – 33, cisapride-(L)-tartrate formulation). This is given as an example how a formulation that lacks pregelatinized starch does not provide controlled release of the active drug substance, but in fact releases it very fast (column 20, lines 41-49). In effect, Vandecruys demonstrates that formulations comprising hydrophilic polymers alone cannot be controlled release formulations. In fact, Vandecruys teaches a person of ordinary skill in the art away from using hydrophilic polymers alone in a controlled release formulation but would need pregelatinized starch as a release rate controller.

The Examiner's assertion that the (non Prior art) Dilantin® PI, in light of Vandecruys, somehow makes the invention claimed in the instant Application obvious does not consider the invention as a whole, but focuses solely on the term 'powder blend' in the claims. Neither does it consider the fact that Vandecruys teaches away from using hydrophilic polymers as rate controlling ingredients.

The examination guidelines for determining obviousness under 35 U.S.C. § 103 issued by the U.S.P.T.O. in view of the Supreme Court Decision in KSR International Co. v Teleflex Inc. (72 Fed. Reg. 57526-35) states "combining known prior art elements is not sufficient to render the claimed invention obvious if the results would not have been predictable to one of ordinary skill in the art.[48] 'When the prior art teaches away from combining certain known elements, discovery of successful means of combining them is more likely to be nonobvious[49].'" (72 Fed. Reg. 57529; citations omitted). In the

present case, even if the Dilantin® PI and Vandecruys could somehow be combined by a person ordinarily skilled in the art to prepare a controlled release formulation of phenytoin sodium, there would have been no prediction or expectation of success without using pregelatinized starch, as Vandecruys emphasizes. The instant Application claims a composition wherein hydrophilic polymers are used as the only release rate controlling agents in order to achieve extended release of phenytoin sodium (Examples 1-6).

Neither Dilantin® PI nor Vandecruys teaches a controlled release phenytoin formulation that includes hydrophilic polymers acting as the release rate controlling agents. Even if either could be read to teach one of skill in the art to make the extended release formulation claimed in this Application, it would be taught based only on impermissible hindsight using the Applicant's application for the teaching to select the limitations of the claims pending in this Application and ignoring the overriding teachings of Vandecruys.

The Applicants believe that the arguments presented hereinabove make it clear that claims 1, 6, 7, 9-13, 16-27, 45-46 and 49-51are not obvious over Dilantin® PI in light of Vandecruys and respectfully request the Examiner to withdraw the 103(a) rejection.

Rejection under 35 U.S.C. § 103(a) over Straub et al. (US Patent 6,395,300)

Claims 1, 6, 7, 9, 11-13, 17-19, 26-27 and 49-51 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Straub et al (US Patent 6,395,300, referred as a Straub hereinafter). The Applicants respectfully traverse.

Straub discloses formulation of low aqueous solubility drugs in porous matrix forms which enhance the dissolution of the drug in aqueous media (abstract and column 2, lines 16-20). This has been achieved by using a process that necessarily involves the lengthy and detailed process limitations of: dissolution of the drug in a volatile solvent; adding a pore forming agent; and then removing the solvent and pore forming agent from the solution to leave the porous matrix behind (examples provided in Straub). The compositions of the present invention do not dissolve phenytoin sodium in any solvent, does not involve the addition of a pore forming agent, does not involve removal of the solvent and the pore forming agent, and does not result in a porous matrix. In fact the composition of the present invention is not a matrix but a powder.

Straub discloses capsules containing the powder obtained by the above process. The powder which is used to fill the capsules in the Straub disclosure is a porous matrix which results in enhanced solubility. Straub does not mention anywhere about extended or sustained release formulations. In fact, Straub states that one of objectives of her invention is to provide compositions that enhance the dissolution rate of drugs. All the examples provided by Straub (Figures 1-8) show that this is indeed the case.

On the other hand, the powder which is used to fill the capsule in the present invention is a powder blend which results in extended release in aqueous media. The present invention claims an extended release formulation. This is exactly the opposite of what is taught by Straub. The Applicants submit that Straub does not disclose or teach any extended release composition or a process to make such a composition and Straub's teachings are not relevant to the invention claimed herein.

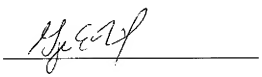
The Applicants respectfully request that the rejection of claims 1, 6, 7, 9, 11-13, 17-19, 26-27 and 49-51 under 35 U.S.C. § 103(a) as being unpatentable over Straub be withdrawn.

The Applicants note the Examiner's comments that it would have been obvious to a person of ordinary skill in the art to filter or pass the powder through a mesh prior to filling the capsules in order to obtain a uniform particle size for the powder. The Applicants have amended the claims to eliminate the process step of screening the powder through a mesh in independent claims 1 and 25.

Conclusion

For the reasons stated above, the Examiner is urged to pass claims 1, 6, 7, 9, 11-13, 17-19, 26-27 and 49-51 to issue. Authorization is hereby given to charge any fees or credits due in connection with this Response to Office Action to Deposit Account No. 50-0912. For purposes of fees, Applicants are a large entity.

Respectfully submitted,



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